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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,914	05/30/2006	Christian Mauran	05091104	8708

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EXAMINER	
HORNBERGER, JENNIFER LEA	
ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
03/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,914	MAURAN ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-38* is/are pending in the application.

4a) Of the above claim(s) *19-24 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Claims 25-37 in the reply filed on 11/05/2009 is acknowledged. The traversal is on the ground(s) that Herberger fails to disclose the common combined inventive features of claims 1 and 25. Examiner respectfully disagrees. Herberger discloses the injection support (4), lens placed flat on the projection support, and a rigid flask (64) containing the bath of solution and the lens constitute a sterilized assembly (paragraph 51). Applicant argues that container of Herberger is not sterilized, and thus, the assembly is not sterilized. However, as currently claimed the elements included in "the assembly" have not been defined. Herberger discloses a sterilized assembly which comprises the injection support, lens, and solution. Applicant argues that no separate search would be required to examine both the method and the device claims. Examination of the method of packaging a hydrophilic lens would require a search at least in Class 422 (Chemical apparatus and process disinfecting, deodorizing, preserving, or sterilizing)/subclass 26 (using direct steam contact to disinfect). However, examination of the device would not require a search in this class/subclass.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 25 recites the limitation "the assembly" in line 23. There is insufficient antecedent basis for this limitation in the claim. It is unclear which elements of the invention “the assembly” includes.

5. Claim 32 recites the limitation “it includes” in line 2. It is unclear which element of the invention is meant by “it”

6. Claim 34 recites the limitation “it includes” in line 2. It is unclear which element of the invention is meant by “it”

7. Claim 35 recites the limitation “it includes” in line 2. It is unclear which element of the invention is meant by “it”

8. Claim 35 recites the limitation “unlockable means”. The word unlockable is unclear because it may mean "capable of being unlocked" or "not capable of being locked". For examination purposes, the examiner has treated this limitation as a “locking means". Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 25, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzocco (US 4,423,809) in view of Eagles et al. (US 5,616,148).

Regarding claim 25, Mazzocco discloses a device for packaging and conserving in a sterile condition a flexible hydrophilic intraocular lens (col. 4, ln. 33), comprising: an injection support (24); a flexible hydrophilic intraocular lens (23) placed on the injection support (24); a packaging enclosing at least the lens, the injection support and a volume of solution for

conserving the lens which bathes the lens and keeps it hydrated, wherein: the injection support (24) is adapted receive and carry the lens flat; the lens is carried flat on the injection support (24) and immersed in a bath of liquid conserving solution contained in a rigid liquid-tight flask (21) which is closed, the assembly is in a sterilized condition (col. 4, ln. 44-63). Mazzocco fails to disclose the injection support including an implantation end through which the lens can be slid and ejected for implantation, said injection support being adapted to be associated with an injection device including a thruster piston able to push the lens toward an implantation end of the injection support and the injection support adapted to carry out folding of the lens prior to the ejection of the lens via the implantation end. Eagles et al. discloses an injection support (14) which is adapted to receive and carry the lens flat, the injection support including an implantation end (16) through which the lens can be slid and ejected for implantation, said injection support adapted to be associated with an injection device (12) including a thruster piston (18) able to push the lens toward the implantation end of the injection support (Fig. 11-12), wherein the injection support is adapted to carry out folding of the lens prior to ejection of the latter via the implantation end (col. 4, ln. 43 - col. 5, ln. 2) to safely compress the lens for delivery through a small incision in the eye. It would have been obvious to one of ordinary skill in the art to substitute the injection support of Mazzocco with the injection support (and the associated injection device) of Eagles et al. in order to permit controlled compression of the deformable hydrophilic lens so that it may be inserted through a small incision in the eye.

Regarding claims 27, Mazzocco modified by Eagles et al. disclose the injection support is adapted to carry out folding by a simple translational movement imparted to the lens when the latter is pushed towards the implantation end (col. 4, ln. 43-64).

Regarding claim 29, Mazzocco modified by Eagles et al. disclose the injection support is carried removably by a stopper for closing the rigid flask (Mazzocco, col. 5, ln. 15-16).

Regarding claim 37, Mazzocco modified by Eagles et al. disclose the injection support (14) includes an adapter bush (22) forming a receptacle for the lens, the bush being adapted to able to carry and receive different models of lens, and to be mounted in a cylindrical end portion of the injection support (14; Fig. 11).

11. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzocco (US 4,423,809) in view of Eagles et al. (US 5,616,148) as applied to claim 25 above, and further in view of Bazell et al. (US 3,930,580).

Regarding claim 26, Mazzocco modified by Eagles et al. disclose autoclaving the rigid flask containing the injection assembly and the lens (4, ln. 44-63), but fail to disclose the rigid flask is enclosed in an outer packaging envelope. Bazell et al. disclose a steam sterilizable packaging envelope for maintaining medical and surgical instruments in sterile condition (see abstract). It would have been obvious to one of ordinary skill in the art to provide the device of Mazzocco modified by Eagles et al. in an outer packaging envelope in order to prevent contamination of the system prior to use.

Regarding claim 28, Mazzocco modified by Eagles et al. disclose the injection support is adapted to carry out folding by a simple translational movement imparted to the lens when the latter is pushed towards the implantation end (col. 4, ln. 43-64).

12. Claims 25, 27, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eagles et al. (US 5,616,148) in view of Mazzocco (US 4,423,809) and Feingold et al. (US 5,728,102).

Eagles et al. disclose a device for packaging and conserving in a sterile condition a flexible intraocular lens comprising: an injection support (14) which is adapted to receive and carry the lens flat (Fig. 12; col. 2, ln. 43-44), the injection support including an implantation end (16) through which the lens can be slid and ejected for implantation, said injection support

adapted to be associated with an injection device (12) including a thruster piston (18) able to push the lens toward the implantation end of the injection support (Fig. 11-12), wherein the injection support is adapted to carry out folding of the lens prior to ejection of the latter via the implantation end (col. 4, ln. 43 - col. 5, ln. 2); a flexible lens (30) placed on the injection support (14; Fig. 11), the hollow cylindrical body (12) forms an axial end stop which prevents premature extraction of the thruster piston (18) from the hollow cylindrical body (Fig. 7).

Eagles et al. fail to disclose a hydrophilic lens and a rigid flask enclosing at least the lens, the injection support and a volume liquid solution which bathes the lens and keeps it hydrated. Mazzocco discloses a flexible hydrophilic intraocular lens (23) placed on the injection support (24); a packaging enclosing at least the lens, the injection support and a volume of solution for conserving the lens which bathes the lens and keeps it hydrated, wherein: the injection support (24) is adapted receive and carry the lens flat; the lens is carried flat on the injection support (24) and immersed in a bath of liquid conserving solution contained in a rigid liquid-tight flask (21) which is closed, the assembly is in a sterilized condition (col. 4, ln. 44-63). Mazzocco discloses the flexible hydrophilic lens has memory characteristics which enable the lens to be deformed during delivery and then return to its original configuration, full size and fixed focal length after insertion into the eye (col. 2, ln. 3-17 and col. 7, ln.27-32 of US Patent 4,573,998 which is incorporated by reference in col. 1, ln. 7-12 and col. 4, ln. 31-35). It would have been obvious to one of ordinary skill in the art to replace the lens in the device of Eagles et al. with the flexible hydrophilic lens of Mazzocco since the lens of Mazzocco provides the advantage of being able to return to its original shape, size, and focal length after deformation of the lens and insertion into the eye. Mazzocco discloses hydrating the lens during storage is advantageous because it eliminates the step of removing the lens from the packaging and converting the optical parameters of the lens in air to equivalent measurements when the lens is

placed in the eye (col. 2, ln. 3-34). In configuring the device of Eagles et al. to deliver a hydrophilic lens, it would have been obvious to one of ordinary skill in the art to maintain at least the lens and the injection support in the conserving solution inside a rigid flask as suggested by Mazzocco in order permit inspection of the optical parameters of the lens without removal of the lens from the injection support.

Eagles et al. modified by Mazzocco fail to disclose the injection support associated with an injection device, wherein the rigid flask and the cylindrical body of the injection device are adapted to be fixed to one another, the injection support extending into the liquid conserving fluid in the rigid flask. Feingold et al. disclose preloading the lens and pre-assembling the injection system prior to packaging is advantageous because it reduces amount of packing and eliminates the step of loading the lens into the cartridge and injecting device which could potentially cause damage to the lens (col. 4, ln. 65 - col. 5, ln. 13). It would have been obvious to one of ordinary skill in the art to modify the device of Eagles et al. to pre-load and pre-assemble injection system (attach the injection support containing the lens to the injection device) in order to reduce amount of packaging and eliminate the risk of damaging lens during the step of loading the lens into the injecting device. Further, it would have been obvious to screw the mouth of the rigid flask to the distal end of the hollow body of the injection device, in place of the cap, during assembly of the device in order to seal the flask and maintain the solution inside the flask.

13. Claims 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eagles et al. (US 5,616,148) in view of Mazzocco (US 4,423,809) and Feingold et al. (US 5,728,102) as applied to claim 33 above, and further in view of Figueroa et al. (US 5,873,879).

Regarding claim 34, Eagles et al. modified by Mazzocco and Feingold et al. fail to disclose a seal adapted to be interposed between the axial end stop of the hollow cylindrical body and a sealing block of the thruster piston when in its retracted end position of the hollow cylindrical body. Figueroa et al. disclose a thruster piston having a seal (proximal seal 120) interposed between the axial end of a hollow cylindrical body and a sealing block (distal seal 120) of the thruster piston. Figueroa et al. discloses the seal and sealing block provide a level of resistance to provide more controlled operation of the plunger and prevent inadvertent movement of the thruster piston (col. 5, ln. 47-53). It would have been obvious to one of ordinary skill in the art to modify the thruster piston of Eagles et al. to include a seal and a sealing block to prevent inadvertent movement of the piston.

14. Claims 25, 27, 30, 31, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figueroa et al. (US 5,873,879) in view of Mazzocco (US 4,423,809).

Figueroa et al. disclose a device for packaging and conserving in a sterile condition a flexible intraocular lens comprising: an injection support (22) which is adapted to receive and carry the lens flat (Fig. 19; col. 4, ln. 22-35), the injection support including an implantation end (95) through which the lens can be slid and ejected for implantation, said injection support adapted to be associated with an injection device including a thruster piston (18) able to push the lens toward the implantation end of the injection support (Fig. 19-20), wherein the injection support is adapted to carry out folding of the lens prior to ejection of the latter via the implantation end (col. 4, ln. 60 - col. 5, ln. 25); a flexible lens (12) placed on the injection support (14; Fig. 11), the thruster piston (18) includes a non rotationally symmetrical operating stem (Fig. 2-4), wherein the hollow cylindrical body has an axial end provided with a non-rotationally symmetrical opening having a shape matching that of the operating stem (col. 3, ln. 38-55), wherein the operating stem is so mounted as to be able to be rotated about its longitudinal axis

between a locked position in which it cannot pass through the opening and an unlocked position in which it can pass through the opening.

Figueroa et al. fail to disclose a hydrophilic lens and a packaging enclosing at least the lens, the injection support and a volume liquid solution which bathes the lens and keeps it hydrated. Mazzocco discloses a flexible hydrophilic intraocular lens (23) placed on the injection support (24); a packaging enclosing at least the lens, the injection support and a volume of solution for conserving the lens which bathes the lens and keeps it hydrated, wherein: the injection support (24) is adapted receive and carry the lens flat; the lens is carried flat on the injection support (24) and immersed in a bath of liquid conserving solution contained in a rigid liquid-tight flask (21) which is closed, the assembly is in a sterilized condition (col. 4, ln. 44-63). Mazzocco discloses the flexible hydrophilic lens has memory characteristics which enable the lens to be deformed during delivery and then return to its original configuration, full size and fixed focal length after insertion into the eye (col. 2, ln. 3-17 and col. 7, ln.27-32 of US Patent 4,573,998 which is incorporated by reference in col. 1, ln. 7-12 and col. 4, ln. 31-35). It would have been obvious to one of ordinary skill in the art to replace the lens in the device of Figueroa et al. with the flexible hydrophilic lens of Mazzocco since the lens of Mazzocco provides the advantage of being able to return to its original shape, size, and focal length after deformation of the lens and insertion into the eye.

Figueroa et al. discloses pre-assembling and preloading the injection device (i.e. the lens loaded in the injection support and the injection support attached with the injection device), but fail to disclose a rigid flask and the cylindrical body of the injection device are adapted to be fixed to one another, the injection support extending into the liquid conserving fluid in the rigid flask. Mazzocco discloses hydrating the lens during storage is advantageous because it eliminates the step of removing the lens from the packaging and converting the optical

parameters of the lens in air to equivalent measurements when the lens is placed in the eye (col. 2, ln. 3-34). In configuring the device of Eagles et al. to deliver a hydrophilic lens, it would have been obvious to one of ordinary skill in the art to maintain at least the lens and the injection support in the conserving solution inside a rigid flask as suggested by Mazzocco in order permit inspection of the optical parameters of the lens without removal of the lens from the injection support. Further, it would have been obvious to screw the mouth of the rigid flask to the distal end of the hollow body of the injection device, in place of the cap, during assembly of the device in order to seal the flask and maintain the solution inside the flask.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
03/10/2010

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